Richardson-Vicks Inc. v. The Upjohn Co. (CA FC) 44 USPQ2d 1181

Richardson-Vicks Inc. v. The Upjohn Co.

U.S. Court of Appeals Federal Circuit
44 USPQ2d 1181

Decided September 26, 1997
No. 96-1214, -1237

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Secondary considerations generally (§ 115.0907)

Federal district court erred by concluding that evidence of unexpected results was "irrelevant" to issue of obviousness, since it is well established that all evidence of non-obviousness must be considered when assessing patentability, and that Patent and Trademark Office must consider comparative data in specification in determining whether claimed invention provides unexpected results, and since district court should have given appropriate weight to evidence of unexpected results in arriving at its judgment of obviousness.

2. Patentability/Validity -- Obviousness -- Combining references (§ 115.0905)

Patentability/Validity -- Obviousness -- Secondary considerations generally (§ 115.0907)

Claims directed to cough and cold medication comprising ibuprofen and pseudoephedrine combined in single form such as tablet or elixir would have been obvious to one of ordinary skill in art at time of invention, since claimed combination was clearly suggested by prior art products which combined analgesic such as acetaminophen or aspirin with decongestant pseudoephedrine in single unit dosage, since ibuprofen had been prescribed in combination with pseudoephedrine in separate doses, since likelihood that ibuprofen would be approved as over-the-counter medicine created strong motivation to combine claimed ingredients in single unit dosage, and since unexpected results and commercial success of claimed invention, although supported by substantial evidence, do not overcome clear and convincing evidence of obviousness.

JUDICIAL PRACTICE AND PROCEDURE

3. Procedure -- Jury trials (§ 410.42)

Advantages of using special verdicts pursuant to Fed.R.Civ.P. 49(a) are well documented in all areas of law, but given nuances of patent law combined with added complications of technology, advantages of special fact verdicts are even more pronounced; in many cases counsel would be well advised to request special verdicts, and in any event trial judges may exercise their broad authority over their trials by utilizing this procedural device.

Particular patents -- Chemical -- Cough remedy

4,552,899, Sunshine, Laska, and Siegel, cough/cold mixtures comprising non- steroidal anti-inflammatory drugs, judgment of invalidity affirmed.

Case History and Disposition:

Appeal from the U.S. District Court for the District of Delaware, Robinson, J.

Action by Richardson-Vicks Inc. against The Upjohn Co., McNeil PPC Inc., and Johnson & Johnson for patent infringement. From grant of judgment as matter of law that patent in suit is invalid for obviousness, plaintiff appeals, and defendant Upjohn Co. cross-appeals. Affirmed.

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Harry J. Roper, Raymond N. Nimrod, and Aaron A. Barlow, of Roper & Quigg, of Chicago, for defendants-appellees McNeil-PPC Inc. and Johnson & Johnson.

Judge:

Before Archer, chief judge, and Michel and Plager, circuit judges.

Opinion Text

Opinion By:

Plager, J.

In this case, a jury found the patent on a popular cough and cold formula not invalid for obviousness and not unenforceable. Subsequently, the trial judge overturned the jury verdict. Plaintiff appeals the trial judge's action. Because the trial judge acted within the scope of her authority in granting judgment as a matter of law ("JMOL"), and on all the facts of record reached the correct conclusion of invalidity for obviousness, the judgment is affirmed.

I. Background

Plaintiff Richardson-Vicks Inc. ("RVI") is the assignee of Reexamination Certificate B1 4,552,899 ("the '899 patent"). The patent is addressed to an over-the-counter ("OTC") medicine that combines, in various ratios, two well-known ingredients, the analgesic ibuprofen and the decongestant pseudoephedrine. The combination is sold for the relief of cough, cold, and flu symptoms.

Claims 36, 37, 47, and 48 were asserted at trial. Claim 36 is a composition-of-matter claim which recites a 1.5:1 to 8:1 dose ratio range of ibuprofen to pseudoephedrine. Claim 37, also a composition-of-matter claim, which depends from claim 36, requires 200 mg of ibuprofen and 30 mg of pseudoephedrine. Claims 47 and 48 are method-of-use claims which correspond, respectively, to claims 36 and 37. The claims each require that the ibuprofen and pseudoephedrine be present in a "combinatory immixture," which the trial judge understood to mean in a single unit dosage, such as a single tablet or capsule.

Defendants market OTC medicines -- Motrin IB Sinus(Registered) and Sine-Aid IB Sinus(Registered) --which contain the same ingredients in similar ratios. At the close of evidence, the trial court pursuant to Federal Rule of Civil Procedure 50 found as a matter of law that defendants' accused products infringed the asserted claims of the '899 patent. That finding is not at issue, so the only questions on appeal relate to the validity and enforceability of the patent.

The original patent application was filed on April 9, 1984 and the patent issued on November 12, 1985. In 1990, RVI requested reexamination of the patent in light of certain Japanese publications. Independently, McNeil-PPC, Inc. ("McNeil"), which is owned by Johnson & Johnson, requested reexamination, citing additional prior art not considered by the examiner in issuing the original patent. Both requests were granted by the United States Patent and Trademark Office ("PTO") on the ground that, as required by statute, each raised "a substantial new question of patentability." *See* 35 U.S.C. Section 303 (1994). Subsequently the two reexaminations were merged into a single reexamination proceeding pursuant to 37 C.F.R. Section 1.565(c). A reexamination certificate was ultimately issued on October 20, 1992.

In 1993 RVI filed a complaint in the United States District Court of Delaware, charging Upjohn, McNeil, and Johnson & Johnson (collectively "defendants") with infringement of claims 36-37 and 47-48 of the '899 patent. Defendants denied liability and counterclaimed for a declaratory judgment that the patent is invalid, not infringed, and that intervening rights bar recovery.

Defendants later moved for summary judgment that the asserted claims are invalid due to prior invention of a third party, that the claims are invalid because they are anticipated or obvious, and that the claims are unenforceable because of patent misuse, arguing that RVI had impermissibly expanded the physical and temporal scope of the '899 patent with anti-competitive effect. The trial court denied all of these motions.

The case proceeded to trial. As noted above, the trial judge granted RVI's motion for judgment of infringement as a matter of law. The questions of validity and enforceability, however, were left to the jury. By verdict rendered May 10, 1995, the jury found, *inter alia* , that the defendants had failed to prove that the claims were invalid for obviousness or prior invention, or that RVI had impermissibly broadened the scope of the '899 patent so as to constitute patent misuse. The jury then awarded RVI a reasonable

royalty of seven percent of the infringing sales.

Following the adverse verdict, defendants renewed their motion for JMOL under Fed. R. Civ. P. 50(b) or, in the alternative, for a new trial under Fed. R. Civ. P. 59. The trial court concluded that there was "no legally sufficient evidentiary basis for a reasonable jury to have found for plaintiff on the issues of obviousness and prior invention." Accordingly, the judge granted the defendants' renewed motion for JMOL on both counts. In the alternative, the court conditionally granted the defendants' motion for a new trial on the issue of obviousness should its judgment be overturned on appeal, but denied the motion for a new trial on the issue of prior invention. The trial court also awarded defendants intervening rights in the event that the JMOL was overturned on appeal. In view of our upholding on the ground of obviousness the trial court's judgment of invalidity, we need not address any of the other questions raised by the appeal.

II. Discussion

A. *Standard of Review*

RVI states the general rule that, in reviewing a jury's verdict on a motion for JMOL, the question before the trial court is whether the jury verdict is supported by substantial evidence. That of course refers to whether the factual findings of the jury, expressed or implied in the verdict, are supported by substantial evidence in the record. RVI argues that on appeal of the grant of JMOL, the appellate court applies the same standard anew, without deference to the trial court's judgment in the matter, citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.* , 806 F.2d 1565, 1 USPQ 1081 (Fed. Cir. 1986), so that its burden in this case is only to show that the jury verdicts are supported by substantial evidence. *Brief for*

Plaintiff at 31.
The difficulty with RVI's position is that, although the argument has merit when the issue is purely one of fact, it does not follow when the issue involves a question of law. It is black letter law that the ultimate question of obviousness is a question of law. *See Graham v. John Deere Co.* , 383 U.S. 1, 17, 148 USPQ 459, 467 (1966) (*citing Great A. & P. Tea Co. v. Supermarket Equip. Co.* , 340 U.S. 147, 155, 87 USPQ 303, 309 (1950)); *In re Donaldson Co.,* 16 F.3d 1189, 1192, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994) (*in banc*); *Texas Instruments Inc. v. United States Int'l Trade Comm'n* , 988 F.2d 1165, 1178, 26 USPQ2d 1018, 1028 (Fed. Cir. 1993). And we review that legal question without deference to the trial court. *See Gardner v. TEC Sys., Inc.* , 725 F.2d 1338, 1344, 220 USPQ 777, 782 (Fed. Cir. 1984) (district court's conclusion on obviousness "is one of law and subject to full and independent review in this court").
At the same time, it is well understood that there are factual issues underlying the ultimate obviousness decision. *See Graham* , 383 U.S. at 17-18, 148 USPQ at 467. These so-called *Graham* factors include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) certain secondary considerations. *Id.* That an obviousness determination stands upon the relevant facts of the case does not convert the ultimate conclusion of obviousness from one of law into one of fact.
In analyzing the correctness of a JMOL overturning a jury verdict, we must consider the facts before the trial court, and then determine whether the trial court's ultimate judgment on obviousness is correct as a matter of law. Determining the facts and how they bore on the jury's view of the case is made considerably more problematic when, as in the case before us, the only information we have about the jury's views are contained in a general verdict. 1
Nevertheless, in re-creating the facts as they may have been found by the jury, and in applying the *Graham* factors to the case, we assess the record evidence in the light most favorable to the verdict winner, in this case

RVI, *Newell Co. v. Kenney Mfg. Co.*, 864 F.2d 757, 765, 9 USPQ2d 1417, 1423 (Fed. Cir. 1988) ("Judges must accept the factual findings, presumed from a favorable jury verdict, which are supported under the substantial evidence/reasonable juror standard."), though this does not mean that we are free to abdicate our role as the ultimate decision maker on the question of obviousness. That decision remains within our province. *See Structural Rubber Prod. Co. v. Park Rubber Co.* , 749 F.2d 707, 718-19, 203 USPQ 1264, 1273 (Fed. Cir. 1984) ("it is the duty of the appellate court to be satisfied that the law has been correctly applied to the facts regardless of whether the facts were determined by judge or jury").
B. *Obviousness*
Claim 36, which is representative of the other independent claim, reads:
A pharmaceutical composition of matter for use in the treatment, management or mitigation of the pain component of cough, cold, cold-like and/or flu symptoms in a mammalian organism, said composition comprising[:]
a sympathomimetically, analgesically and anti-inflammatorily effective amount ranging from 25 mg to 600 mg of ibuprofen or pharmaceutically acceptable salt thereof,
in combinatory immixture with 5 mg to 120 mg of pseudoephedrine or pharmaceutically acceptable salt thereof, and wherein the ratio by weight of said NSAID (i) to said sympathomimetic amine (ii) ranges from about 1.5:1 to about 8:1.

Thus, claim 36 defines a cough and cold medication comprising two ingredients -- ibuprofen and pseudoephedrine -- in "combinatory immixture." (As earlier noted, claim 37, which depends from claim 36, further limits the amount of ibuprofen to 200 mg and to 30 mg of pseudoephedrine; claim 48 claims a method of treating cough and cold symptoms using the claimed combination of claim 36, while claim 49 is a similar method claim incorporating claim 37.) The question then is whether this composition would have been obvious in view of the prior art. Since the patentee RVI does not argue the validity of the dependent claims separately, their validity will stand or fall with independent claim 36. *See Stratoflex, Inc. v. Aeroquip Corp.* , 713 F.2d 1530, 1536, 218 USPQ 871, 877 (Fed. Cir. 1983).
The trial court reviewed the claims, the written description, and the prosecution history, and concluded that the phrase "combinatory immixture" required "the two ingredients in a single form such as a tablet or elixir." Neither party seriously disputes this definition. Having conducted a similar review of the evidence relevant to claim construction, we find no error in this definition and adopt it as our own.
The obviousness issue therefore boils down to whether one of ordinary skill in the art would have combined the two ingredients into a single form. We must therefore consider the four *Graham* factors, interpreted in light of the jury verdict. In doing so, we remain cognizant of the statutory presumption of validity, 35 U.S.C. Section 282, as well as that "the facts to support a conclusion of invalidity must be proven by clear and convincing evidence," *Ryko Mfg. Co. v. Nu- Star, Inc.* , 950 F.2d 714, 716, 21 USPQ2d 1053, 1055 (Fed. Cir. 1991). *Scope and Content of the Prior Art:*
The obviousness of a patent claim is determined "at the time the invention was made." 35 U.S.C. Section 103. April 9,

1984 is the date the original patent application was filed. The trial court considered and rejected an earlier date of conception by the inventors, Drs. Sunshine, Laska, and Siegel. RVI does not now challenge that finding. Accordingly, the relevant prior art is that art existing prior to April 9, 1984, the date of constructive reduction to practice of the invention.

There is no dispute about the scope and content of the prior art. The most relevant prior art includes two cough and cold formulations. The first is a combination of acetaminophen and pseudoephedrine sold as a single unit dosage under the brand name CO-TYLENOL(Registered). Pseudoephedrine was also combined with aspirin in a unit dosage for treating cough and cold symptoms. The combination of an analgesic (aspirin or acetaminophen) and a decongestant (pseudoephedrine) was known to be particularly effective for treating sinus headaches because both drugs help to alleviate the associated pain. The analgesic operated in the normal manner to relieve pain, while the decongestant relieved pain by reducing swelling and congestion on the sensitive membranes in the area of the sinuses. Doctors had been taught in medical school to treat sinus headaches by prescribing both analgesics and decongestants together. In this case there was evidence that doctors had in fact prescribed ibuprofen in combination with pseudoephedrine, albeit not in a "combinatory immixture."

Differences Between the Claimed Invention and the Prior Art: The difference between the other single unit dosage cough and cold products such as CO-TYLENOL and the claimed invention is that the former used a different analgesic (i.e., acetaminophen) than the claimed invention. Thus the "combinatory immixture" included one but not both of the ingredients specified in the patent. The difference between the doctor prescribed combinations and the claimed invention is that the doctors' prescriptions assumed that the named analgesic, ibuprofen, and the pseudoephedrine would be in physically separate tablets. Thus, the prescribed medications were not in "combinatory immixture," as that phrase in the patent is defined. *Level of Ordinary Skill in the Art:* The parties do not dispute the level of ordinary skill. Defendants assert that one of ordinary skill in the art is a person with an M.D. or Ph.D., citing to a paper filed by RVI with the PTO asserting this to be the required level of skill. RVI does not challenge this assertion. There is therefore no dispute as to the level of skill in the art. *Evidence of Secondary Considerations:* RVI relies heavily on evidence of secondary factors to overcome the strong showing of the prior art. Primary among that evidence is the results of so-called "synergy" between the ibuprofen and the pseudoephedrine. By that RVI means that the "analgesic and anti-inflammatory response" of the combinatory immixture is greater than what would be predicted based on the two ingredients separately. To prove this claim, RVI commissioned a test by an independent testing laboratory. The laboratory conducted tests on mice to measure their response to pain stimuli. A first group of mice was administered ibuprofen and a control group received a placebo. Both were subjected to a pain stimulus. The responses of the treated mice were then compared to the responses of the mice in the control group (i.e., those without ibuprofen). A mouse in the treated group was said to be protected if its pain was less than half of the mean value of the pain responses of the mice in the control group. Based on this data, a dosage was statistically determined that is the amount of ibuprofen that is expected to protect 50% of a group of mice subjected to the same pain stimuli. This dosage is referred to as the "Effective Dosage for 50%" or "ED_{50}" for ibuprofen This procedure was then repeated for pseudoephedrine to produce the ED_{50} for pseudoephedrine. A two dimensional chart was then constructed with the ED_{50} for ibuprofen as a data point on the y-axis and the ED_{50} for pseudoephedrine as a data point on the x-axis. A line connecting these two data points, called the "line of additivity," was then constructed which represented the ED_{50} for various combinations of these two components.

A combination dose lying on the line of additivity was then chosen. This dosage was then administered to a group of mice in a test group who were then challenged by a pain stimulus. The responses of this group were then compared to a control group. The combination dosage of a ratio of ibuprofen to pseudoephedrine of 7:1 lying on the line of additivity protected 80% of the mice tested, instead of the 50% predicted by the line of additivity. This was a statistically significant result, according to the inventors, because it demonstrated that the combination produced greater pain relief than that dictated by the pain relief properties of the two drugs individually. In other words, the two drugs produced a "synergistic" effect.

During reexamination, the PTO gave significant weight to the test results. Initially the examiner rejected the claims on the ground of obviousness:

The issue that the Examiner considers central to the ultimate issue of patentability is whether or not aspirin and any one of the claimed propionic acid NSAIDs would have been reasonably expected by a person of ordinary skill in this art to be interchangeable in a cough/cold combination containing a sympathomimetic amine decongestant.

The patent owner maintains that the skilled artisan would have not considered aspirin and the propionic acid NSAIDs

interchangeable in cough/cold preparations containing a sympathomimetic amine.
The Examiner, however, cannot concur.
Paper No.18, dated February 18, 1992. The examiner confirmed his rejection under Section 103 in an "Advisory Action." *See* *Manual of Patent Examining Procedure* Section 714.13, at 700-68 (6th ed. 1995).
Although the test results were before the examiner when he issued the Advisory Action, they were deemed not to rebut the *prima facie* case of obviousness because the test results were not "commensurate in scope with the claimed subject matter." In response, the patentees drafted a complete new set of claims (39-68) that were "commensurate in scope" with the test results. The examiner allowed these new claims over the prior art. The examiner explained his change of mind:

This conclusion is supported by the declarations filed under
37 CFR 1.132 and the data submitted therewith on January 14, 1992 and April 22, 1992 which establish that when certain propionic acid NSAID ingredients are combined with certain sympathomimetic amine ingredients in a specific range of proportions, an unexpectedly superior degree of pain relief results. The prior art fails to teach or suggest such results and the claims are commensurate in scope with the evidence submitted. Thus, the claims are deemed to be patentable over the cited prior art.
Thus, the Examiner placed singular reliance on the evidence of synergy to allow the claims.
RVI also put on evidence of commercial success. The proffered evidence included annual sales of the patented product of some $48 million, with gross profit margins of between 67% and 79%, within three years of the product's introduction. There was also evidence to show that the growth of the claimed ibuprofen/pseudoephedrine product has been in excess of 30% per year since its introduction while during the same period the overall OTC market has grown at only 10% per year.
RVI also put on evidence of "skepticism" by others concerning the invention. Drs. Murcek and Brooks testified that combining ibuprofen and pseudoephedrine into a single tablet having a fixed ratio would be "illogical" and "impossible" to use in a clinical setting. Although both prescribed ibuprofen and pseudoephedrine together, neither had combined them into a single unit dosage. The reason they gave in their testimony was that their practices require flexibility in treating patients, which requires them to prescribe the two drugs in varying ratios. As one of the doctors stated, " [t]he ratio could be as low as one to five or as high as one to thirty."
RVI also suggests that the prior art "teaches away" from the claimed invention and put on evidence to support this. In particular, RVI produced scientific evidence that ibuprofen actually causes congestion. Therefore, according to RVI, it would be illogical to use ibuprofen in a formula intended to reduce congestion such as a cough and cold formula.
Even though the evidence of unexpected results based on the mice experiments was dispositive in the PTO, it was considered "irrelevant" by the trial court because "the alleged synergistic property of the patented combination was unknown at the time of Dr. Sunshine's invention" and "several other OTC ibuprofen manufacturers similarly arrived at the claimed invention without knowledge of any synergy." In rejecting the evidence of unexpected results, the trial court quoted from and apparently relied on *In re Soni* , 54 F.3d 746, 34 USPQ2d 1684 (Fed. Cir. 1995), for support. The trial court then went on to decide the ultimate issue of obviousness "without regard to any evidence of synergy." On appeal, defendants "do not dispute RVI's contention that synergy was proved for the claimed combination."
As with the evidence of unexpected results, the trial court also discounted the evidence of commercial success. Quoting from *Kansas Jack, Inc. v. Kuhn* , 719 F.2d 1144, 219 USPQ 857 (Fed. Cir. 1983), the trial court concluded that the "evidence of commercial success proffered by plaintiff is limited to sales data, and does not include evidence of 'market share, of growth in market share, of replacing earlier units sold by others or of dollar amounts, and no evidence of a nexus between the sales and the merits of the invention.' "
[1] In discounting the evidence of unexpected results, the trial court read more into *In re Soni* than is there. Indeed, in that case the court reiterated the well-established rule that "all evidence of nonobviousness *must be considered* when assessing patentability," and further that "the PTO *must consider* comparative data in the specification in determining whether the claimed invention provides unexpected results." *In re Soni* , 54 F.3d at 750, 34 USPQ2d at 1687 (emphasis added).
Rather than permit a court to ignore evidence of unexpected results, *In re Soni* makes clear that such evidence must be considered in evaluating the obviousness of a claimed invention. In arriving at its judgment regarding whether the claimed invention would have been obvious, the trial court should have given appropriate weight to the evidence of unexpected results. *See* *Stratoflex* , 713 F.2d at 1538, 218 USPQ at 879 ("It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case, patent cases included. Thus evidence arising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness."); *In re Soni* , 54 F.3d at 750, 34 USPQ2d at 1687; *In re Chu* , 66 F.3d 292, 298, 36 USPQ2d 1089,

1094 (Fed. Cir. 1995); *In re Oetiker* , 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki* , 745 F.2d 1468, 1471-72, 223 USPQ 785, 787 (Fed. Cir. 1984) ("All evidence on the question of obviousness must be considered, both that supporting and that

rebutting the *prima facie* case.") This proposition holds not only in *ex parte* proceedings before the PTO but also in *inter partes* proceedings in the district courts. *See* *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.* , 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984) (error for district court to ignore evidence of unexpected results in deciding obviousness); *Kansas Jack* , 719 F.2d at 1150, 219 USPQ at 861 (" *all* evidence touching the obvious-nonobvious issue [must] be considered before a conclusion is reached on the issue").
This does not necessarily mean that the trial court's ultimate judgment was incorrect. Evidence of secondary considerations, including evidence of unexpected results and commercial success, are but a part of the "totality of the evidence" that is used to reach the ultimate conclusion of obviousness. *Kansas Jack* , 719 F.2d at 1151, 219 USPQ at 862. In some cases such evidence is the most probative of obviousness. *See, e.g.* , *Stratoflex* , 713 F.2d at 1538, 218 USPQ at 879. The existence of such evidence, however, does not control the obviousness determination. *See Newell* , 864 F.2d at 768, 9 USPQ2d at 1426 ("First, as indicated, obviousness is not a factual inference; second, although these factors must be considered, they do not control the obviousness conclusion.") (citations omitted); *Ryko* , 950 F.2d at 719, 21 USPQ2d at 1058 (the weight of secondary considerations may be of insufficient weight to override a determination of obviousness based on primary considerations). Therefore, we must consider all of the evidence under the *Graham* factors before reaching our decision.
[2] In this case we agree with the trial court that, when all the factors are considered, the claims would have been obvious to one of ordinary skill in the art. The prior art combinations of an analgesic (aspirin or acetaminophen) and a decongestant (pseudoephedrine) in a single unit dosage were known to be particularly effective for treating sinus headaches because both drugs help to alleviate the associated pain. Ibuprofen was a known analgesic that was interchangeable with either aspirin or acetaminophen. Moreover, ibuprofen was prescribed in combination with pseudoephedrine by the doctors who testified. The only difference between the prescribed combination and the patented invention is that the prescription was not contained in a single tablet. Such a combination was clearly suggested by the prior art including CO-TYLENOL(Registered), which combined an analgesic with pseudoephedrine into a single tablet. In fact, it was so combined by a third party, AHP, in October of 1983, prior to the date of invention. 2 The unexpected results and commercial success of the claimed invention, although supported by substantial evidence, do not overcome the clear and convincing evidence that the subject matter sought to be patented is obvious.
There also exists another fact that created a strong motivation to combine the two ingredients into a single unit dosage, i.e., in "combinatory immixture." In 1983, numerous prior art publications announced that the Food and Drug Administration ("FDA") would approve ibuprofen as an over-the- counter medicine, subject to voluntary compliance with certain advertising restrictions. *See* "Low-dose ibuprofen may enter OTC analgesic market," *Medical World News* at 14-5 (Sept. 26, 1983). Those publications indicated that the FDA would likely approve dosages in the range of 200 to 400 mg, precisely within the range of the claimed invention. The OTC industry anticipated that ibuprofen would quickly begin displacing acetaminophen and aspirin as the preferred analgesic because ibuprofen was known to be as or more effective a pain reliever and also produced "fewer gastrointestinal effects than aspirin." *Id.* The motivation to substitute ibuprofen for either acetaminophen or aspirin in the prior art "combinatory immixtures" to produce the claimed combination would have been particularly strong for the ibuprofen manufacturers because it allows them to strengthen the name brand recognition through so- called "line extensions." These line extensions allow the ibuprofen manufactures to use their brand names under which ibuprofen is sold (e.g., Motrin IB(Registered)) in other products (e.g., Motrin IB Sinus(Registered)) and thereby increase the name recognition of the underlying ibuprofen product.
The evidence of commercial success is equally unpersuasive. Even if we infer that the jury found that the claimed invention was a "commercial success," this evidence

does not convince us that the invention was not obvious. The advantages of ibuprofen were well known by doctors and patients alike. Those advantages included reduced gastrointestinal side effects and greater pain relief than aspirin. It is not surprising then that the claimed invention was highly successful and may have displaced the prior art combinations because consumers preferred ibuprofen to aspirin or acetaminophen.
The fact that doctors wanted greater flexibility in prescribing this combination does not teach away from the claimed combination. It merely recognizes that doctors must treat a variety of differently situated patients including children and adults. The OTC market, in contrast, aims at a much broader market. As a result, the dosages are much lower than

on the other hand, might prescribe different dosages based on a variety of other factors, including the severity of the condition, the weight of the patient, etc., even though each patient is a member of the broad class. RVI's other evidence of secondary factors is equally unpersuasive.3

[3] Sorting through the record in a case such as this when the issue is the correctness of a jury verdict is made considerably more difficult by the absence of specific findings by the jury. The effort by the successful plaintiff to support the jury verdict in its favor is also made more difficult. The preferred route would have been to submit the underlying factual issues to the jury in the form of a special verdict under rule 49(a). That rule provides:

(a) Special Verdicts. The court may require a jury to return only a special verdict in the form of a special written finding upon each issue of fact. In that event the court may submit to the jury written questions susceptible of categorical or other brief answer or may submit written forms of the several special findings which might be made under the pleadings and evidence; or it may use such other method of submitting the issues and requiring the written findings thereon as it deems most appropriate. The court shall give to the jury such explanation and instruction concerning the matter thus submitted as may be necessary to enable the jury to make its findings upon each issue. . . .

Fed. R. Civ. P. 49(a). The reasons for using this procedural device are obvious and well documented in all areas of the law. For example, one noted scholar long ago described the benefits as follows:

The special verdict compels detailed consideration. But above all it enables the public, the parties and the court to see what the jury really has done. The general verdict is either all wrong or all right, because it is inseparable and inscrutable. A single error completely destroys it. But the special verdict enables errors to be localized so that the sound portions of the verdict may be saved and only the unsound portions be subject to redeterminations through a new trial.

Sunderland, *Verdicts, General and Special* , 29 Yale L.J. 253, 259 (1920). *See generally* 5A Jeremy C. Moore et al., *Moore's Federal Practice* Para. 49.02 (2d ed. 1996) (discussing problems associated with general verdicts). Given the nuances of patent law combined with the added complications of technology, the advantages of a special fact verdict are even more pronounced. This court early made the point that " [t]he utilization of Rule 49(a) appears to us as a particularly useful tool in conserving judicial resources and in effectuating the Congressional policy expressed in the patent laws." *Structural Rubber* , 749 F.2d at 724, 223 USPQ at 1277. The Supreme Court recently emphasized that patent cases are particularly well suited for special verdicts. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.* , 117 S. Ct. 1040, 1053 n.8, 41 USPQ2d 1865, 1875 n.8 (1997) (" [I]n cases that reach the jury, a special verdict and/or interrogatories on each claim element could be very useful in facilitating review, uniformity, and possibly post-verdict judgments as a matter of law."). In many cases counsel would be well advised to request special verdicts, and in any event trial judges may exercise their broad authority over their trials by utilizing this procedural device.

III. Conclusion

On the basis of the record before us, the judgment of the trial court is

AFFIRMED.

Each party to bear its own costs.

Footnotes

Footnote 1. The question posed to the jury, and answered by it, was: *Invalidity - Obviousness*

Do you find that defendants Upjohn and McNeil have proven by clear and convincing evidence that any of the claims 36, 37, 47 and 48 of plaintiff Richardson-Vicks' B1 '899 patent is invalid because the differences between the subject matter of the claims and the prior art as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

We express no opinion on the legal correctness of this question as stated since that issue has not been raised by the parties.

Footnote 2. Defendants allege that this October 1983 combination renders the claims invalid under 35 U.S.C. Section 102(g) because the invention was "invented by another." This issue was submitted to the jury and the jury found that although AHP conceived of their invention on October 1983 by manufacturing 30,000 tablets of the claimed drug, they did not actually reduce this invention to practice until August 1985 after the clinical testing had been completed. Defendants ask us to reverse this finding on the grounds that, as a matter of law, AHP reduced its invention to practice in October 1983 when it manufactured the drug. We need not reach this issue given our holding that the claims are invalid under Section 103.

Footnote 3. RVI puts great emphasis on the following statement in an Upjohn advertisement:
Will somebody please put the two [ibuprofen and pseudoephedrine] into one combination formula that will make my sinus pain and congestion go far, far away?
This advertisement, according to RVI, represents "industry acclaim" of the patented invention that constitutes "strong objective evidence of nonobviousness." We fail to appreciate the significance of this statement which is intended to generate interest in the product, not prove its superiority.

- End of Case -
